In Reply to USPTO Correspondence of May 24, 2007

Attorney Docket No. 3896-031736 (P-6004)

REMARKS

Applicants acknowledge with appreciation the courtesies extended to Applicants' attorney, Lara A. Northrop, in a telephone call on July 18, 2007, during which the Examiner clarified that the present Office Action is non-final.

Claims 1-9 and 23-26 are pending in this application, with claims 1 and 23 in independent form.

Claims 1-6 and 9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,982,842 to Hollister (hereinafter "Hollister") in view of U.S. Patent No. 5,599,318 to Sweeney et al. (hereinafter "Sweeney"). Also, claims 7 and 23-26 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister in view of Sweeney further in view of U.S. Patent No. 5,197,954 to Cameron (hereinafter "Cameron"). Further, claim 8 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister in view Sweeney further in view of U.S. Patent No. 6,077,253 to Cosme (hereinafter "Cosme"). Each of these rejections is respectfully traversed for the reasons set forth herein.

Rejection of Claims 1-6 and 9 under 35 U.S.C. § 103(a) - Hollister in view of Sweeney

The Examiner asserts, on page 4 of the Office Action, that:

Hollister discloses a device, as described above, that teaches all the limitations of the claims except Hollister does not expressly disclose an annular skirt, a safety shield and a collar; wherein the safety shield and a collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.

To rectify this deficiency, the Examiner applies Sweeney as disclosing:

[a] device comprising wherein an annular skirt, a safety shield and a collar; wherein the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.

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Applicants' independent claim 1 recites, inter alia:

a holder housing <u>adapted</u> to receive a sample collection tube within <u>a rearward end</u> ... including ... an annular skirt extending about the needle receiving port; and a safety shield pivotably attached to a collar, <u>said collar having an opening therethrough</u> for receiving a <u>needle cannula therethrough</u>, the collar being received <u>between</u> the annular skirt and the needle receiving port . . . (Emphasis added.)

A. The Combination of Hollister and Sweeny <u>does not</u> Disclose or Suggest all of the limitations of Applicants' Independent Claim 1

The Examiner acknowledges that Hollister does not disclose an annular skirt, or a safety shield and a collar that can be radially rotated without axial movement of the collar. As Hollister does not disclose an annular skirt, Hollister also does not disclose or suggest a collar being received between the annular skirt and the needle receiving port. Sweeney discloses in column 7, lines 29-32, and shown in Fig. 18, "Base member 132 is rotationally engaged with the hub (128) in a snap-fit arrangement involving the engagement of inwardly facing annular rib 203 on the base member and annular recess 204 on the hub." As shown in Fig. 18 of Sweeney, the needle cannula 121 passes through the rib 203 which is connected to the base member 132. However, Sweeny does not disclose or suggest a "collar having an opening therethrough for receiving a needle cannula therethrough, the collar being received between the annular skirt and the needle receiving port" as recited by Applicants' independent claim 1.

In addition, Applicants' claim 1 recites, *inter alia*, "a holder housing adapted to receive a <u>sample collection tube</u> within a rearward end" (Emphasis added.). Hollister discloses in column 4, lines 25-28, "At the distal end of hub 16 is, for this embodiment, a circumferential extension 18, extending orthogonally to the longitudinal length of base 2, for <u>mating with the internal threads of a syringe.</u>" (Emphasis added.) Similarly, Sweeney discloses in column 7, lines 17-18 "hub 128 is integrally formed with <u>syringe barrel 162 of hypodermic syringe 161"</u>. (Emphasis added.) Both Hollister and Sweeney are specifically directed to a fixed engagement with a syringe. Applicants respectfully submit that neither Hollister nor Sweeney disclose or suggest a holder housing adapted to receive a sample collection tube within a rearward end as recited by Applicants' independent claim 1.

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The Examiner contends that it would be obvious to merely provide the apparatus of Hollister with a rotatable collar, such as disclosed in Sweeney. However, the structures of Hollister and Sweeney are entirely different, and are certainly different that the claimed structure. Even if one skilled in the art attempted to combine Hollister and Sweeney, there is no clear way to combine the shield of Sweeney with the structure of Hollister to produce the presently claimed invention. Neither Hollister, nor Sweeney, nor the combination of Hollister and Sweeney disclose or suggest a collar being received between the annular skirt and the needle receiving port, with a safety shield pivotally attached to the collar, as recited in Applicants' independent claim 1. Accordingly, even if Hollister and Sweeney were combined, the resulting combination is structurally different from the structure of Applicants' presently claimed invention.

Accordingly, even if the teachings of Hollister and Sweeney are combined, the resulting combination does not teach all of the limitations of Applicants' claim 1. Dependent claims 2-5 and 9 depend directly or indirectly from claim 1 and are believed patentable for the reasons stated herein. Applicants request reconsideration and withdrawal of the rejection of claims 1-6 and 9.

Rejection of Claims 7 and 23-26 under 35 U.S.C. § 103(a) – Hollister in view of Sweeney in view of Cameron

As a preliminary matter, Applicants' claim 7 depends from independent claim 1 and is believed patentable for the reasons stated above. The teachings of Cameron do not rectify the basic deficiencies of the combination of Hollister and Sweeney with respect to Applicant's independent claim 1, nor does the Examiner provide any evidence to the contrary. Accordingly, Applicants submit that claim 7 is patentable and request reconsideration and withdrawal of the rejection of claim 7.

With respect to claims 23-26, the Examiner repeats the teachings of Hollister and Sweeney recited above on page 5 of the Office Action, and further states on page 6 that:

Hollister as modified by Sweeney discloses an assembly, as described above, that teaches all the limitations of the claims except Hollister as modified by Sweeney et al. does not explicitly

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teach an annular skirt that substantially encloses an open end of the hook arm.

To rectify this deficiency, the Examiner applies Cameron as disclosing:

[a] holder assembly wherein an annular skirt 72 abuts a hook arm 84 when a holder housing 12 and a collar 72 are in an attached position; wherein the annular skirt substantially encloses an open end of a hook arm.

Applicants' independent claim 23 recites, inter alia:

a holder housing <u>adapted to receive a sample collection tube</u> within a rearward end . . . and a collar . . . <u>wherein the annular skirt abuts</u> the hook arm when the holder housing and the collar are in an <u>attached position</u>.

B. The Combination of Hollister and Sweeny and Cameron <u>does not</u> Disclose or Suggest all of the limitations of Applicants' Independent Claim 23

The Examiner acknowledges that Hollister does not disclose an annular skirt, or a safety shield and a collar that can be radially rotated without axial movement of the collar. As Hollister does not disclose an annular skirt, Hollister also does not disclose or suggest that the annular skirt abuts the hook arm when the holder housing and the collar are in the attached position. Sweeney discloses in column 7, lines 21-24, "needle shield 135 hingedly attached to base member 132 through the action of hinged pins 133 on the base member and hinge holes 138 in the needle shield." Sweeney further discloses in column 7, lines 29-32, "Base member 132 is rotationally engaged with the hub (128) in a snap-fit arrangement involving the engagement of inwardly facing annular rib 203 on the base member and annular recess 204 on the hub." As such, the attachment of the safety shield of Sweeney does not disclose an annular skirt abutting a hook arm when the holder housing and collar are in an attached position, as recited in Applicants' independent claim 23.

The Examiner has applied Cameron as rectifying the deficiencies of Hollister and Sweeney; however, the Examiner has mischaracterized the boss 72 of Cameron, identified in column 6, line 65, as <u>both</u> the annular skirt and the collar. Applicants' independent claim 23 clearly recites both an annular skirt and a collar as <u>separate elements</u>. As such, neither Hollister, nor Sweeney, nor Cameron, taken alone or in combination disclose or suggest that the "annular

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skirt abuts the hook arm when the holder housing and the collar are in an attached position" as recited in Applicants' independent claim 23.

In addition, Applicants' claim 1 recites, *inter alia*, "a holder housing adapted to receive a <u>sample collection tube</u> within a rearward end". (Emphasis added.) The arguments set forth above with respect to Hollister and Sweeney are repeated herein with respect to independent claim 23. Furthermore, Cameron discloses in column 1, lines 7-9 that the invention disclosed therein "relates generally to . . . a hypodermic syringe having a needle which snaps off and folds back into a protective groove in the side of the syringe. . ." Accordingly, Hollister, Sweeney and Cameron are each specifically directed to a fixed engagement with a syringe or a syringe structure. Applicants respectfully submit that neither Hollister nor Sweeney nor Cameron disclose or suggest a holder housing adapted to receive a sample collection tube within a rearward end as recited by Applicants' independent claim 23.

Accordingly, even if the teachings of Hollister and Sweeney and Cameron are combined, the resulting combination does not teach all of the limitations of Applicants' claim 23. Dependent claims 24-26 depend directly or indirectly from claim 23 and are believed patentable for the reasons stated herein. Applicants request reconsideration and withdrawal of the rejection of claims 23-26.

Rejection of Claim 8 under 35 U.S.C. § 103(a) – Hollister in view of Sweeney in view of Cosme

Applicants' claim 8 depends from independent claim 1 and is believed patentable for the reasons stated above. The teachings of Cosme do not rectify the basic deficiencies of the combination of Hollister and Sweeney with respect to Applicants' independent claim 1, nor does the Examiner provide any evidence to the contrary. Accordingly, Applicants submit that claim 8 is patentable and request reconsideration and withdrawal of the rejection of claim 8.

SUMMARY

In view of the above remarks, it is apparent that none of the references disclose or suggest a device as set forth in Applicants' claims. Accordingly, the present application is

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deemed to be in condition for allowance. Reconsideration and withdrawal of the rejections and favorable allowance of the application are therefore respectfully solicited.

Should the Examiner have any questions regarding any of this information, the Examiner is invited to contact Applicants' undersigned representative by telephone at (412) 471-8815.

Respectfully submitted,

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